REPENCED

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ONTAINS NO

APR 2 0 2007

Joseph F. Williams President and CEO Micro Systems Technologies, LLC 315 Bowman Dr. Fairborn, OH 45324 Phone: 937-271-4214

Re: TERA R07-01

Dear Mr. Williams:

Fax: 765-496-6489

This letter confirms the oral notification that the TSCA Experimental Release Application (TERA) referenced above has been reviewed and approved by the U.S. Environmental Protection Agency (EPA). The review period for this TERA ends on April 29, 2007. Pursuant to CFR 725.270(a)(2), upon receipt of this letter you may proceed with the field tests described in the TERA, including the one scheduled on April 24, 2007.

According to 40 CFR 725.270(c), you are limited to the terms and conditions described in the TERA. Any deviations from these terms would require further notification to EPA under TSCA. In addition you are required to comply with the attached emergency notification requirements, which are incorporated into this TERA approval pursuant to 40 CFR 725.270(b)(3) and (c)(32).

EPA has determined, pursuant to 40 CFR 725.270(b)(2), that the research and development activity for this microorganism as described in the TERA application, does not present an unreasonable risk of injury to health or the environment. The decision has therefore been made to approve the experimental release of the genetically engineered microorganism (GEM) identified as *Pseudomonas putida* TVA8, based on minimal environmental release and minimal hazard. EPA expects that, to mitigate exposure, appropriate personal protective equipment and engineering controls will be use during manufacturing, processing, and use of the GEM, which includes the enclosure of the organism in the sensing device during field trials, as

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LE COPY 617-813/99826 As noted in the preamble to the final rule, Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act (62 FR 17910, 17928 (April 11, 1997)), EPA will forward a copy of the decision on this TERA to the appropriate state regulatory authorities. For the upcoming Fort Carson, CO, field test the state contact is Laura Quakenbush, Colorado Department of Agriculture (phone 303-239-4100, fax 303-239-4177, E-mail laura.quakenbush@ag.state.co.us). You must inform us of the locations and dates of the remaining field test locations at least 1 month before those tests occur so that we can notify other state regulatory authorities.

If you have any questions or comments regarding this TERA, please contact Dr. Jeremiah Duncan at 202-564-1117. You may also contact our Biotechnology Coordinator, Karen Chu at 202-564-8773.

Sincerely,

Rebecca Cool, Chief

New Chemicals Notice Management Branch

Chemical Control Division

Office of Pollution Prevention and Toxics

U.S. Environmental Protection Agency

Attachment

### **ATTACHMENT**

# EMERGENCY NOTIFICATION RE: TERA R-07-1

(a) <u>Notification Requirement</u>. Within 24 hours of the occurrence of any of the conditions listed in paragraph (b), the Company must notify all the persons listed in paragraph (c) of the items listed in paragraph (d).

## (b) Conditions Requiring Notification.

- (1) The Company has reason to believe that it has failed, or will fail, to comply with any material term of the TSCA §5(e) Order or TERA approval document; or
- (2) There is an accidental spill or an unauthorized environmental release of any amount of the new microorganism, or unauthorized human exposure to the new microorganism; or
- (3) The company obtains any new information (or is notified by EPA) indicating that despite compliance with the terms of the TSCA §5(e) Order or TERA approval document, the new microorganism may cause significant adverse reactions to health or the environment, or presents a substantial risk of injury to health or the environment.

### (c) Who to Notify.

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- (1) The EPA New Chemicals Notice Management Branch in Washington, D.C. (Telephone: 202-564-8999; FAX 202-564-9490);
- (2) The EPA Regional Biotechnology Coordinator for the pertinent test site (see http://www.epa.gov/oppt/biotech/pubs/biocontx.htm);
- (3) The appropriate state regulatory authority (for the Fort Carson, CO, field test, the contact is Laura Quakenbush, Colorado Department of Agriculture (phone 303-239-4100, fax 303-239-4177, E-mail laura.quakenbush@ag.state.co.us));
- (4) The appropriate local emergency response unit; and
- (5) The EPA representative on the Regional Response Team (see 40 C.F.R. §300.115).

### (d) Contents of Notice. The notice must explicitly state:

- (1) That it is an "emergency notification required by a TSCA §5(e) Order or TERA approval document";
- (2) The identification number of the submission to EPA pertaining to the new microorganism (Microbial Commercial Activity Notice, or TERA), and identity of the new microorganism;
- (3) The nature of the emergency condition;
- (4) The status of any remedial response measures taken;
- (5) The name, phone number, and address of a responsible Company representative who should be contacted for further discussion regarding the emergency situation.

(e) Reports of Substantial Risk. Any information on the new microorganism which reasonably supports the conclusion that the new microorganism presents a substantial risk of injury to human health or the environment is required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987). The report shall reference the appropriate identification number for the new microorganism and shall contain a statement that the new microorganism is subject to a TSCA §5(e) Order or TERA approval document. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 29, 1991).

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